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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,546	07/10/2003	Katharina Brodka-Pfeiffer	1/1367	4289

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EXAMINER	
DAVIS, BRIAN J	

ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,546	BRODKA-PFEIFFER ET AL.	
	Examiner	Art Unit	
	Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☒ Claim(s) *4 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/03; 2/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 4 and 5 are objected to because of the following informalities: the claims do not end with a period (after the table). Claims must begin with a capital letter and end with a period. MPEP 608.01(m). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,874,063, cited by the applicant in the IDS. The reference teaches micronized salbutamol sulfate suitable for inhalation (example 8; column 1 line 13).

Claim 7 is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2112.02. The examiner also points out that to be patentable, a

novel form of an old compound must possess a new utility or a utility of a different type. A mere improvement in properties does not render a novel form of an old compound patentable. In re Weijland, 587 OG 3, 33 CCPA 837, 154 F.2d 133; 1946 CD 175, 69 USPQ 86; *Ex parte Hald*, Paper 15 in US 2,647,145.

Relatedly, there are a number of decisions holding that where the purification of an old product results in a mere change in degree in its properties, the purified form is unpatentable. *Ex parte Windhaus*, 15 USPQ 45 (POBA 1931); *In re Ridgeway*, 76 F.2d 602, 25 USPQ 202 (CCPA 1935); *In re Mertz*, 97 F.2d 599, 38 USPQ 143 (CCPA 1938); In re Macallum, 102 F.2d 614, 41 USPQ 146 (CCPA 1939); *In re King*, 107 F.2d 614, 43 USPQ 400 (CCPA 1939); *Ex parte Sparhawk*, 64 USPQ 339 (POBA 1945); *In re Weijlard*, 154 F.2d 133, 69 USPQ 86 (CCPA 1946); *In re Johnson*, 94 F.2d 978, 37 USPQ 75 (CCPA 1938); *Ex parte Cavillito*, 89 USPQ 449 (POBA 1950); *Ex parte Snell*, 86 USPQ 496 (POBA 1950); *In re Fisher*, 307, F.2d 948, 135 USPQ 22 (CCPA 1962); *Ex parte Hartop*, 139 USPQ 525 (POBA 1962); *Ex parte Siddiqui*, 156 USPQ 426 (POBA 1966); *Ex parte Schmidt-Kastner*, 153 USPQ 473 (POBA 1963).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,709,884.

Applicant claims a process for providing a stable crystalline form of salbutamol sulfate suitable for inhalation (claim 1). The dependent claims further refine the process.

US 5,709,884 teaches a process for providing a stable crystalline form of a fine grain substance, or substance mixture, suitable for inhalation. The process consists of three steps (if the substance is not a mixture): 1) micronization by any conventional

method to a particle size suitable for inhalation of <10μm; 2) conditioning by treatment with water or water-containing vapor; 3) drying (abstract).

Salbutamol sulfate is taught as one of a set of preferred starting materials (column 4 line 13). The conditioning is carried out at 0-100°C, preferably 10-50°C (column 3 line 21). The relative humidity in the conditioning step is above 35%, preferably above 50% and most preferably above 75% (column 3 line 24). The authors explicitly point out that the conditioning step is carried out at a temperature and relative humidity which suppresses the glass temperature of the substance below the process temperature (column 3 line 14). The time required varies considerably depending on batch size, relative humidity, packing, etc. and may be from minutes to days (column 3 line 27).

Applicants distinguish over the prior art in that a particular particle size distribution is required (90% of the particles must be under 4.6μm; claim 1). However, absent some showing of criticality, the examiner considers this distribution a mere obvious engineering expediency, given that the prior art explicitly teaches that the speed of the conditioning step depends on size, packing, etc. One of ordinary skill in the art would have been motivated to decrease the particle size to increase the speed of the conditioning step and therefore the overall efficiency of the process.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
June 26, 2004